APPLICATION FOR

UNITED STATES LETTERS PATENT

FOR

AIRLESS VENT VALVE

BY:

KENNETH A. JONES
DARIN JOHN MILLER

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December 3, 2003
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AIRLESS VENT VALVE

BACKGROUND OF THE INVENTION

1. Cross-Reference to Related Application:

This application claims the benefit of and priority to a U.S. Provisional Patent Application No. 60/430,390 filed December 3, 2002, the technical disclosure of which is hereby incorporated herein by reference.

2. Technical Field:

The present invention relates to pump systems for open heart surgery, and particularly to valves used in such surgery.

3. Description of Related Art:

In the performance of open heart surgery, the heart is generally bypassed and the patient's blood circulation is maintained by the use of a heart-lung machine such as a cardioplegia pump or similar apparatus. During such an operation, blood often finds its way into the left ventricle of the heart. This blood must be removed to avoid distending the left ventricle, which can make resuscitation of the heart at the end of the surgery difficult or impossible.

Drainage of the left ventricle is achieved by inserting a drainage cannula into the left ventricle. This cannula is used to drain blood either by gravity or by use of a pump or a combination of the two. The blood is typically directed through one or more conduits to a cardiotomy reservoir, and then to an oxygenator which oxygenates the blood. The blood flow is then directed back to the patient.

The rate at which a left ventricle pump operates determines the rate at which fluid is removed from the left ventricle. If the rate of pumping is to slow, fluid will accumulate in the left ventricle despite the pump, while if the rate of pumping is too great, the mouth of the drain tube can suck against the tissue of the heart, causing trauma.

One typical way to deal with this issue is to a positive-displacement aspiration pump and to control its operational speed throughout the surgical procedure. To control the level of suction applied, a negative pressure relief valve is used in the suction line between the pump and the

heart. Such a valve typically controls the negative pressure by venting air into the suction line downstream of the valve if the suction line becomes occluded or otherwise develops too great a negative pressure. Negative pressure relief valves often include a check valve safety feature which prevents reverse flow of clued toward the heart.

Venting air into the suction line is not desirable, as air introduced into the blood flow system can introduce particulates or other pollutants, and can also increase chances of coagulation in the system. Such valves must also be monitored visually in order to determine if an occlusion in the vent line has occurred so that the occlusion can be dealt with and venting of the left ventricle restored without damage to the heart.

The art would therefore benefit from a vent valve that allows relief of both positive and negative pressure and which does not entrain air into the extracorporeal circuit.

SUMMARY OF THE INVENTION

The present invention provides a system for venting excess fluid from a patient during heart surgery. In a preferred embodiment, the innovative system includes a valve between a pump and the patient. The preferred valve allows reduction of negative pressure in the line by allowing entry of fluid from a reservoir into that line when excess negative pressure occurs. In preferred embodiments, the valve has two inlets and one outlet. A first inlet accepts fluid from the patient, and a second inlet accepts fluid from a reservoir only when negative pressure exceeds a predetermined amount. An outlet allows fluid to pass from the patient to the pump, such as a vent pump.

Another innovative aspect of the present invention is the reduction of homolysis by providing fluid access at angles which reduce turbulence within the valve. By promoting smooth fluid passage through the valve, blood cells undergo less stress and are more likely to pass through the valve undamaged.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features believed characteristic of the invention are set forth in the appended claims. The invention itself, however, as well as a preferred mode of use, further objectives and advantages thereof, will best be understood by reference to the following detailed description of an illustrative embodiment when read in conjunction with the accompanying drawings, wherein:

Figure 1 shows an extracorporeal circuit consistent with a preferred embodiment.

Figure 2 shows a detail of the innovative valve according to a preferred embodiment.

Figure 3 shows the innovative valve in the context of the vent line and venous reservoir line.

Figure 4 shows a detail of the innovative valve according to a preferred embodiment.

DETAILED DESCRIPTION OF THE INVENTION

The description of the present invention has been presented for purposes of illustration and description, and is not intended to be exhaustive or limited to the invention in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art. The embodiment was chosen and described in order to best explain the principles of the invention, the practical application, and to enable others of ordinary skill in the art to understand the invention for various embodiments with various modifications as are suited to the particular use contemplated.

The present innovations are described with reference to the figures.

Figure 1 shows a patient **102** with apparatus for performing heart surgery where the blood is circulated in an extracorporeal circuit. Four pumps are shown, an arterial pump **104**, a sucker pump **106** for manual suction, a vent pump **108** which typically removes excess fluid from the left ventricle of the heart, and a cardioplegia pump **110** which provides cardioplegia solution and potentially other fluids to the patient. Also shown in the diagram are reservoirs, among them the venous reservoir **112** and the cardiotomy reservoir **114**.

The present inventive concept is preferably employed as a valve **116** between vent pump **108** and the patient **102**. The vent pump **108** connects to the patient via a line **118** which ends in a vent cannula **120** inserted into the left ventricle of the patient. The vent pump **108** is typically used to drain excess fluid from the left ventricle during surgery. Some means must be employed to prevent retroflow of fluid back into the patient, and to prevent excess vacuum from developing in the vent line **118** in case the vent cannula **120** or the line **118** itself becomes occluded. Valve **116** is therefore located in the vent line **118**.

In a preferred embodiment, valve **116** is an airless vent valve which not only prevents retroflow back toward the patient and excess vacuum in the line **118**, but it also preferably prevents excess positive pressure from building in the line **118** as well. In a preferred embodiment, the valve **116** achieves this goal without introducing air into the circuit. The valve **116** therefore has a line **122** which provides fluid access to the venous reservoir **112**.

In its preferred operation, valve **116** allows fluid flow from patient **102** to the vent pump **108** but prevents flow in the opposite direction. Valve **116** also allows flow of fluid from venous reservoir **112** toward vent pump **108** in the event that excess negative pressure builds up in line

118. This function is referred to as negative pressure relief or excess vacuum relief of line **118**. Valve **116** also provides positive pressure relief from the line **118** in the event of a buildup of positive pressure. In this event, valve **116** allows flow of fluid from the vent pump **108** toward the venous reservoir **112** (or another appropriate reservoir, depending on the implementation used, such as cardiotomy reservoir **114**).

Inovative valve **116** therefore preferably provides negative pressure relief, positive pressure relief, and retroflow protection. It does this without introducing air into the circuit by allowing fluid to flow into the line **118** when the pressure exceeds a predetermined amount. Valve **116** also preferably offers a visual cue to when it performs these functions. Examples of possible visual cues include but are not limited to: transparency in the valve so that fluid flow can be detected; an electronic detector which monitors flow through the valve and provides an indication such as a display or light; or a mechanical indicator such as a button which pops out when the valve is activated for these functions, for example.

Valve **116** can provide positive pressure relief in other ways, such as by expelling fluid from the valve **116** to open air. this embodiment alleviates the need for a bi-directional flow at one inlet of the valve **116**.

Though **Figure 1** shows the valve **116** connected to venous reservoir **112**, alternative embodiments supply fluid to the valve via line **122** from an alternative source. This alternative source is preferably part of the closed extracorporeal circuit and is not open to atmosphere. Less preferred embodiments use the innovative valve **116** with reservoirs that are open to the atmosphere, but are still within the innovative concepts herein disclosed.

Figure 2 shows a detail of the valve **116**. Valve **116** is shown with three openings, a first inlet **210**, a second inlet **208**, and an outlet **206**. Inlet **210** preferably attaches to a line that connects to reservoir **112** or similar reservoir. Inlet **208** preferably connects to patient **102** via line **118**. Outlet **206** preferably connects to vent pump **108**.

Inlet **208** preferably allows fluid flow only from patient **102** and prevents retroflow toward patient **102**. This is achieved in a preferred embodiment with a one way valve **202** such as a duck billed valve as shown, for example.

If the vent cannula **120** becomes attaches to the tissue of the heart, trauma can result from the suction against tissue. This situation will create negative pressure inside line **118**. Valve **116** relieves such negative pressure by admitting fluid into line **118** via inlet **210**. Inlet **210** includes a

valve **204** that automatically allows fluid flow from reservoir **112** toward vent pump **108** once negative pressure reaches a certain amount. The pressure required to allow this fluid flow is preferably determined by the mechanical structure of valve **116**.

In an alternative embodiment, inlet **210** possesses only a one-way valve and is capable of relieving negative pressure in the line by admitting fluid from source **112**. In this embodiment, valve **204** is preferably implemented as an umbrella valve or other one-way valve that responds to negative pressure on the side of the valve closest to line **118**. When negative pressure in line **118** reaches a predetermined limit, valve **204** responds by admitting fluid into line **118** from source such as venous source **112**. There is preferably a visual indicator function or other means in valve **116** to alert a monitor (human or otherwise) that negative pressure has occurred in the line and that the relief function has begun. For example, valve **116** could have a transparent window near valve **204** which will show when fluid passes through valve **204**. Other indicators can be implemented as well, including electronic monitors and auditory alerts, depending in the implementation.

Valve **204** can also be variable in its response to negative pressure. Instead of a fixed pressure at which valve **204** admits fluid, some embodiments include a variable mechanism to controlling the negative pressure at which valve **204** activates.

Figure 3 shows a simple diagram of the innovative valve system and nearby lines. Valve **116** is located on line **118** between patient **102** and vent pump **108**. If vent cannula **120** becomes occluded, negative pressure builds up in line **118** by action of vent pump **108**. In this instance, the negative pressure in line **118** will cause a valve at inlet **210** to activate, allowing flow from line **122** into line **118** thereby relieving the negative pressure and preventing trauma to heart tissue. Though line **122** is shown linking to venous reservoir **112**, other reservoirs can be used. The reservoir used is preferably part of the extracorporeal circuit and is preferably closed to air.

Figure 4 shows another innovative aspect of valve **116**. This diagram shows inlets **208** and **210** and outlet **206** with their respective axes **208A, 210A,** and **206A**. The axes are represented as being parallel with the direction of fluid flow through each of the orifices. In order to reduce homolysis, the axes **210A** and **208A** enter valve **116** at an angle of less than ninety degrees with respect to one another. Supplying blood flow at angles so that the blood must change direction as little as possible reduces turbulence within the valve and thereby reduces damage to the cells within the blood.

The innovative valve system provides several advantages over prior valve systems, including alleviating the need to entrain air into the extracorporeal circuit, which reduces protein denaturation and activation of coagulation factors. It also reduces homolysis by virtue of the angle at which different flows pass through the valve. By relieving both positive and negative pressure in the line from the same source, no blood is lost from the extracorporeal circuit.